NDA 19-430/S-012

Meridian Medical Technologies, Inc.
2550 Hermelin Drive
St. louis, MO 63144

Attention: Thomas G. Freund
Manager, Regulatory Affairs

27 AUG 2001

Dear Mr. Freund:

Please refer to your supplemental new drug application dated January 25, 2001, received January 26, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for EpiPen and EpiPen Jr. AutoInjectiors.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional packaging configuration for the EpiPen and EpiPen Jr. AutoInjectors. In addition, this supplement provides for revisions in the labeling and patient package insert as well as inclusion of a new trainer patient package insert.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert), patient package insert, immediate container and carton labels submitted January 25, 2001. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ladan Jafari, Regulatory Project Manager, at (301) 827-5584.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research